## 510(k) Summary of Safety and Effectiveness

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Statement	Information supporting claims of substantial equivalence, as defined under the				
	Federal Food, Drug, and Cosmetic Act, respecting safety and effectiveness is				
	summarized below. For the convenience of the Reviewer, this summary is				
	formatted in accordance with the Agency's final rule "510(k) Summaries				
	and 510(k) Statements" (21 CFR 807) and can be used to provide a				
	substantial equivalence summary to anyone requesting it from the Agency.				
	NEW DEVICE NAME: Xtractor				
	PREDICATE DEVICE NAME: Endopouch pro specimen retrieval bag				
Device	The Xtractor device is comprised of a flexible plastic bag with a large, easily				
Description	accessible opening attached to a plastic rod. The handle and opening/closing				
	mechanism allow single hand use.				
Intended Use	The Xtractor is intended for use during general surgical procedures as well as				
	the collection and extraction of tissue specimen such as appendix, gall bladder,				
•	biopsy specimen and other tissues and calculi.				
Indications	The Xtractor is a disposable device used as a receptacle for the collection and				
Statements	extraction of tissue specimens such as appendix, gall bladder, biopsy specimen				
	and other tissues and calculi during laparascopic surgical procedures.				
Technological	The new devices has different technological characteristics as the predicate				
characteristics	device. The form and principle is different but the intended use is the same.				
Performance	Animal and Human testing has been performed to verify that the Xtractor				
Data	meets the performance required. It was determined that the device has a great				
	bag strength and that the principle of operation is quicker than the predicate				
	device.				
Conclusion	Based upon the 510(k) summaries and 510(k) statements (21 CFR 807) and				
	the information provided herein, we conclude that the new device is				
	substantially equivalent to the predicate device under the Federal Food, Drug,				
	Cosmetic Act.				
Contact	Martin Paquette				
	Official Correspondant				
	Groupe Horzone				
	411 Belvédère Sud				
	Sherbrooke Québec				
	Canada J1H 4B7				
Date	January 22, 2001				

Germain Béland

Président

Instruments Médicaux G.B. Inc.

Martin Paquette

Official Correspondant



APR - 9 2001

Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

Instruments Medicaux G. B., Inc. c/o Mr. Martin Paquette
Groupe Horzone
411 Belvedere Sud
Sherbrooke, Quebec
Canada

Re: K010220

Trade/Device Name: Xtractor Regulation Number: 876.1500

Regulatory Class: II Product Code: GCJ Dated: January 19, 2001 Received: January 24, 2001

Dear Mr. Paquette:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Enclosure

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative and Neurological Devices Office of Device Evaluation

Miriam C. Provost

Center for Devices and

Radiological Health

K010220

Instruments Médicaux G.B. inc.

868 des Jardins Fleuris Sherbrooke, Québec Canada JIE 1J5

Téléphone : (819) 566-5689 Fax : (819) 820-9696

Indications for Use Statement

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(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number 100220